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AWARD NUMBER: W81XWH-05-1-0366

TITLE: Short-term Exercise and Prostate Cancer Prevention in African-American Men

PRINCIPAL INVESTIGATOR: Teletia R. Taylor, Ph.D.

CONTRACTING ORGANIZATION: Howard University
Washington, DC 20059

REPORT DATE: April 2006

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE (DD-MM-YYYY) April 2006		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 21 Mar 05 –20 Mar 06	
Short-term Exercise and Prostate Cancer Prevention in African-American Men				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-05-1-0366	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Teletia R. Taylor, Ph.D. E-mail: t_r_taylor@howard.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Howard University Washington, DC 20059				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This study seeks to examine the impact of exercise on serum factors related to prostate cancer in African-American men. Aims and Objectives: 2. To examine the effect of 12 days of aerobic exercise over 4 weeks on PSA levels in African American men. 3. To examine the effect of 12 days of aerobic exercise on free and total testosterone, insulin, IGF1, and SHBG levels in African American men. A total of 40 AA men (ages of 40 – 70 yrs, BMI > 25 and < 35 kg/m2, sedentary) will be randomized into 2 groups 12 days of aerobic exercise (20 participants), or a control group (20 participants). Exercise participants will engage in 12 days of exercise (30 minutes of walking on a treadmill at 50 – 60% of their maximal oxygen consumption (VO2max)). Free testosterone, lipids, glucose, insulin, SHBG, body weight, BMI and body fat composition, anthropometric measurements, height, weight, will be measured before and after the study.					
15. Subject Terms (keywords previously assigned to proposal abstract or terms which apply to this award) Prostate Cancer Risk, African-American, Males					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 17	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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Annual Report
Short-Term Exercise and Prostate Cancer Prevention in African-American Men

Proposal Log Number PC040735, Award Number W81XWH-05-1-0366, HSRRB Log Number A-13283

INTRODUCTION

The aim of this study is to examine the effect aerobic exercise has on serum factors associated with prostate cancer among African American men. The incidence of prostate cancer in African American men is 59% greater than in Caucasian men. In addition, African American men have been reported to have higher levels of PSA and free testosterone. Research suggests that the noted increase in the incidence of prostate cancer among African American men could be related to environmental, lifestyle, and/or genetic factors. The environmental factor of concern and the primary focus of this research is physical activity. Currently, no other research has examined the potential benefits of exercise in the fight against prostate cancer among African American men. The results of this study will serve to develop optimal lifestyle strategies for the reduction of prostate cancer risks.

BODY**Aims and Objectives:**

1. To recruit 40 African-American men between the ages of 40 and 70 who are at increased risk for developing prostate cancer and randomize them into an exercise intervention or control group.
2. To examine the effect of 12 days of aerobic exercise over 4 weeks on PSA levels in African-American men.
3. To examine the effect of 12 days of aerobic exercise on free and total testosterone, insulin, IGF1, and SHBG levels in African-American men.

Hypothesis:

- H1 Twelve days of exercise will reduce PSA levels in African-American men.
H2 Twelve days of exercise will reduce free and total testosterone levels in African-American men.
H3 Twelve days of exercise will reduce insulin levels in African-American men.
H4 Twelve days of exercise will increase SHBG levels of African-American men.

Study Design:

A total of 40 African-American men between the ages of 40 – 70 yrs, from the Howard University Cancer Center prostate screening program that have a BMI ≥ 25 and < 35 kg/m², < 375 pounds, and have been sedentary for at least 6 months (not exercising for more than 20 minutes 2 days a week). Men will be randomized into 2 groups: 12 days of aerobic exercise (20 participants), or a control group (20 participants). All participants will be screened by a physician for cardiovascular disease and will participate in a maximal graded exercise test. The 12 days of exercise will consist of 30 minutes of walking on a treadmill at 50 – 60% of maximal heart rate reserve (HRR). Blood samples will be taken in the morning after an overnight fast on day 2, and day 16, 24 – 36 hours after the last bout of exercise. Serum will be separated from the blood and stored at - 80°C until analyzed. Free testosterone, lipids, glucose, insulin, SHBG, psychosocial

measures, body weight, BMI and body fat, anthropometric measurements, height, and weight will be measured before and after the study.

Proposed Amendments

The following amendments have been approved by the Howard University's IRB. I am requesting that the same amendments be considered by the Department of Defense Human Subjects Review Board.

1. Personnel Change:

The exercise physiologist originally assigned to this project has recently taken a position out of the region. She has recently been replaced by an exercise physiologist, Jennifer Sween, MS. Ms. Sween's biosketch has been included in the packet.

Dr. Peter Gaskin (pediatric cardiologist/ Howard University Hospital) has also been included in this project. Dr. Gaskin will oversee graded exercise testing. Dr. Gaskin's biosketch is also included in the packet.

2. Expand PSA criteria.

Rational: The eligibility criteria allowing only men with PSA levels between 2.5 and 3.9 ng/ml is extremely restrictive for this study. The goal of this study is to examine the effect of exercise in men at risk for prostate cancer. African-American males are at greater risk for prostate cancer compared to all other ethnic groups. To this end, we would like to address all African-American men, regardless of PSA level, as long as they do not have prostate cancer. We will include appropriate diagnostic and digital rectal exam results to confirm the absence of prostate cancer in those who present with elevated PSA levels ($\text{PSA} > 4.0 \text{ ng/ml}$). This change will exponentially expand our pool of potential participants.

3. Allow PSA results to be obtained within a year of enrollment of the study.

Rational: The current study requires PSA levels to be obtained within 6 months of study enrollment. We propose that this requirement be changed to 1 year. Since the American Cancer Society recommends annual PSA screening for African-American men starting at age 45, we suspect that a PSA level report within one year is sufficient for enrollment into this study.

4. Modifying sedentary definition

Rational: The former proposal required persons to be sedentary (exercising less than 20 minutes/2 days a week) for the past 2 years. We are modifying the definition of sedentary to include having exercised less than 20 minutes/2 days a week for the past

6 months. The American College of Sports Medicine defines sedentary behavior as exercising less than 20 minutes/2 days per week without defining duration. The change that we have made from 2 years to six months, therefore is legitimate.

KEY RESEARCH ACCOMPLISHMENTS

1) Study Preparation

- a) IRB
- b) Laboratory Preparation
- c) Study Personnel Meeting

2) Recruitment

- a) HUCC Prostate Cancer Screening:
- b) Physician Offices
- c) Churches
- d) Support Groups
- e) Print Media
- f) Radio
- g) Television
- h) Health Fairs
- i) Presentations
- j) Prostate Screening Grant:

3) Data Collection

4) Study Amendments Approved Since the Inception of Study

5) Seminars/Conferences

REPORTABLE OUTCOMES

1) Study Preparation

IRB: IRB approval was obtained with the acceptance of Dr. Teletia Taylor as the new Principal Investigator on February 25, 2005. This project's award contract was granted March 18, 2005.

Laboratory Preparation: Laboratory supplies (i.e. blood sampling supplies, exercise testing supplies, office supplies and food frequency questionnaires) were ordered and obtained by late April 2005.

Study Personnel Meeting: A meeting of study personnel (PI, physician, exercise physiologist, nutritionist, statistician, cardiologist) took place during the study

preparation phase of this study. As a result of this meeting all study personnel discussed their role in the study as well as logistics for each component of the study.

2) Recruitment

HUCC Prostate Cancer Screening: A strong recruitment effort has been made to promote study enrollment. Our main source of recruitment has come from the Howard Cancer Center monthly prostate screenings. Since this study requires that men have obtained the PSA results within 6 months of enrollment, men who completed screening since October of 2004 were examined for eligibility. To be deemed eligible, men must have had a PSA level of 2.5 ng/ml – 3.9 ng/ml. A total of 54 men from October 2004 and January 2005 had PSA levels of 2.5 ng/ml – 3.9 ng/ml. This total makes up approximately 10% of the total number of men that were screened during this time period. Study flyers were distributed to men at each monthly prostate cancer screening regardless of PSA status. Men were told to call if they were interested in the study and we would contact them at a later date once PSA results had been obtained. Once PSA results were obtained, letters were sent to men who had PSA levels within study criteria range.

Physician Offices: Flyers were placed in HUH Family Practice, Oncology, and Radiology offices.

Churches: Study flyers were sent to area churches. Some churches included the study information in the Sunday bulletins. Flyers were also sent to church based cancer support groups.

Support Groups: Study flyers were been sent to area cancer support groups.

Print Media: An advertisement for this study was placed in the Washington Post and the North West Current.

Radio: The PI of this study participated in a radio interview on WOL 1340 AM (July, 2005) related to exercise and cancer. An advertisement for this study was conducted during this interview.

Television: The PI of this study conducted a television interview on the 9 am news segment of Channel 9 news (CBS) and promoted this study.

Health Fairs: This study was advertised at a number of health fairs. In particular, the study flyers were distributed at the Black Family Reunion (September, 2005). This event drew a large number of area African-American residents. Also, study flyers were distributed at the Channel 4 (NBC) “It’s Your Health” event. This health fair drew a large number of area residents as well. This study was also promoted at a number of church health fairs.

Presentations: The study PI has made several presentations in the Washington DC area regarding this study. The first presentation (September, 2005) was conducted as a part of the American Cancer Society’s “Let’s Talk About It: Prostate Cancer Symposium”. This

symposium was geared toward minority men. Another presentation (October, 2005) was made at the The National Caucus and Center on Black Aged: Take Your Loved One to the Doctor Day”.

Prostate Screening Grant: The Howard University Cancer Center has encumbered external funds from the District of Columbia’s Department of Health to screen 3,500 African-American men for prostate cancer. This screening effort should attract a large number of potential participants to this study.

Recruitment Totals: A total of 54 men responded to our recruitment efforts. Of this number, 5 men were enrolled in the study. 10 men were ineligible due to PSA results outside of study range, 2 men were outside of the age range of study, 1 person exceeded the weight requirement for study, 1 person was diagnosed with prostate cancer, 11 men were physically active, 1 person had uncontrolled diabetes, 1 person had uncontrolled hypertension, 2 men were currently on prostate medication, 1 person had cardiovascular disease, 8 men needed to have PSA levels checked, and 6 men were not able to be reached by telephone after several attempts.

3) Data Collection

The first participant in this study was consented July 19, 2005. A total of 5 participants have been enrolled and consented to date. One person was not able to continue due to failure of the Graded Exercise Test during the laboratory screening session. Another participant chose not to participate because he was unwilling to be placed in the control group. Three participants have successfully completed the study. Two of these participants have been placed in the exercise intervention group and one has been placed in the control group.

4) Study Amendments Approved Since the Inception of Study

The following amendments have been made to the study protocol since the inception of the study. All changes have been approved by (DOD) Human Subjects Research Review Board as well as the HU-IRB (see Attachment).

1. Additional psychosocial surveys have been added to the protocol: The General Health Questionnaire (Goldberg, 1988) and the SF-36 questionnaire (Ware, 1993).
2. We have replaced the Women’s Health Initiative food frequency questionnaire with the Food Frequency Questionnaire (General Form) from the Fred Hutchinson Cancer Research Center.
3. We now allow cigarette smokers to participate in this study.
4. Only persons with a weight of 375 pounds or below are allowed to participate in this study due to the weight limitations of the exercise equipment.

5. We are now scheduling the blood collection and exercise testing on separate days. (Prescreening 1, Blood Draw Visit, 12 Exercise Sessions, Follow-up Visit 1, Blood Draw Visit).
6. We are not administering the three-day food record.

5) Seminars/Conferences

During the past year I have attended the monthly Seminars in Oncology at the Howard University Cancer Center. The lectures given during this seminar focused on a variety of topics including prostate cancer prevention and control. I have also attended HUCC Tumor Board meetings. In June (2005) I attended the 12th Annual Meeting of the Psychoneuroimmunology Research Society (PNRS). This society is an international organization for researchers in a number of scientific and medical disciplines who are interested in the relationship between the immune system, behavior and health. I attended a number of lectures/symposia as well as networked with conference participants. In September (2005) I was awarded a Howard University Travel Grant to attend the 7th Annual International Symposium on Exercise and Immunology. This conference was especially helpful as I was exposed to a wide range of research focusing on the impact of exercise on cancer. I attended a number of lectures on this topic as well as networked with exercise physiologists and immunologists from around the world. I was able to exchange ideas related to laboratory development, instrumentation and research methodology.

CONCLUSIONS

The current study was designed to measure the effects of exercise on serum factors associated with prostate cancer. Data collection has been initiated and several amendments have been proposed to facilitate study completion. I have also been engaged in a variety of educational activities that have broadened my exposure to exercise and prostate cancer research. At the conclusion of this study period, we hope to provide useful information for the lay and scientific community regarding the benefits of exercise on reducing prostate cancer risk.

REFERENCES

Golderberg D, Williams P: A user's guide to the General Health questionnaire. Windsor, UK: NFER-Nelson 1988.

Ware, J. E, (1993). SF-36 Health Survey: Manual and Interpretation Guide. Boston: The Health Institute, New England Medical Center.

APPENDICES

1) Biosketches

Jennifer Sween, MS (Exercise Physiologist)

Peter Gaskin, MD (Pediatric Cardiologist)

2) Amended Consent Form

SUPPORTING DOCUMENTS

N/A

Principal Investigator/Program Director (Last, first, middle): _____

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Sween, Jennifer Caroline		POSITION TITLE Exercise Physiologist	
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)			
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
University of Windsor	B.S.	1998-2002	Kinesiology
Howard University	M.S.	2003-2005	Exercise Physiology

RESEARCH AND PROFESSIONAL EXPERINCE

Fall 2000	Cardiac Research Assistant, YMCA Heart Club, Windsor, Ontario, Canada.
Spring 2001-2002	Cardiac Research Assistant, Windsor-Essex Cardiac Rehabilitation, Windsor, Ontario, Canada.
Fall 2004-2005	Research Assistant, Howard University Exercise Physiology Laboratory, Washington, DC.

ABSTRACTS AND PRESENTATIONS

June 2004	<u>Effects of Physical Activity on an Exaggerated Blood Pressure Response to Exercise in Normotensive Young Adult African-American Women</u> Presented at the 2004 Howard University Graduate School Research Symposium.
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PROFESSIONAL AFFILIATIONS

American Physiology Society

Principal Investigator/Program Director :

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed on Form Page 2.

Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Peter R. Gaskin, M.D.		POSITION TITLE Assistant Professor	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
University of the West Indies, Mona, Jamaica	M.B.B.S	1988	Medicine
Queen Elizabeth Hospital, St. Michael, Barbados	Adv. Diploma	1988-90	Internship
University of the West Indies, Mona, Jamaica		1992	Child Health
The Brooklyn Hospital Center, Brooklyn, New York		M.D.	1994-96
Duke University Medical Center, Durham, NC		1996-99	Pediatric Cardio. Fellow
Duke University Medical Center, Durham, NC		1999-2000	Interventional Pediatric Catheterization Fellow

Positions and Honors.

A. PROFESSIONAL EXPERIENCE

2000-2003 Private Practice, Delaware Pediatrics, St. Michael, Barbados
 2001-2003 Director, Pediatric Intensive Care Unit, Queen Elizabeth Hospital, Barbados
 2001-2003 Part-time lecturer, Faculty of Clinical Medicine & Research, University of the West Indies, Cave Hill Campus, Barbados
 2003-present Assistant Professor in Pediatric Cardiology, Dept. of Pediatrics & Child Health, Howard University
 2004- present Assistant Professor in Cardiology, Dept. of Cardiology, Dept. of Medicine, Howard University
 .

HONORS & AWARDS:

1995-1996 Chief Resident in Pediatrics, Brooklyn Hospital Center, New York
 1996 Third Prize, Vincent Tricomi Resident Research Award, The Brooklyn Hospital Center for Presentation of "Personality Changes During Pediatric Residency"
 1999-2000 Dr. Joe Hargrove/St. Jude Medical Fellowship in Interventional Cardiology

PROFESSIONAL CERTIFICATIONS:

2002 American Board of Pediatrics, Sub-Board, Pediatric Cardiology

1997 American Board of Pediatrics – General Pediatrics

B. Selected peer-reviewed publications (in chronological order).

1. Gaskin PRA, Levett PN et al. Cerebrospinal fluid shunt infection due to *Corynebacterium xerosis*. *Journal of Infection*, 28:323-5, 1994.
2. Gaskin P, Box J, Hasselblad V, Kanter R. Sinus P wave rates in children having congestive heart block. *Pace*, 22:877, 1999 (abst).
3. Gaskin P, O'Laughlin M. Shunt closure with Gianturco-Grifka device. *Catheter Cardiovasc Interv*, 48(4):368, 1999.
4. Gaskin P, Owens S, Talner N, Sanders S, Li J. Clinical auscultation skills in pediatric residents. *Pediatrics*, 105(6):1184-7, 2000.
5. Ungerleider RM; Johnston TA; O'Laughlin MP; Jagers JJ; Gaskin PR. Intraoperative stents to rehabilitate severely stenotic pulmonary vessels. *Ann Thorac Surg*, 71(2):476-81, 2001.

C. Research Support

1. Children's Miracle Network 1997 and further funding in 2000. Cardiovascular Effects of Modified Ultrafiltration in Congenital Heart Disease.
2. Children's Miracle Network 1999. Effects of Microgravity on Cardiac Protein Isoform Expression.
3. Fund for Academic Excellence, Howard University. July 2004. Improving Auscultation Skills in College of Medicine Students, Howard University
4. DC-Baltimore Center to Improve Child Health Disparities. August 2004 – July 2005. Funding for Community Youth Obesity Pilot Project.

Informed Consent Form
Consent for Investigative Procedures
Howard University
Washington, D.C. 20059

Short-Term Exercise and Prostate Cancer Prevention in African-American Men

Project Director: **Teletia R. Taylor, Ph.D.**

The following tests and/or procedures are needed for this project:

Tests & Procedures to be Performed

A. Tests:

- 1) Height, weight, body composition, resting heart rate, and blood pressure
- 2) Treadmill exercise test of peak oxygen uptake at the beginning of the study and one after 12 days of exercise over 4 weeks

B. Procedures

- 1) Completion of informed consent form
- 2) Completion of medical history questionnaire
- 3) Completion of psychosocial questionnaires
- 4) Completion of a physical activity questionnaire
- 5) Treadmill exercise test and blood sample
- 6) Exercise 3 days per week for 4 weeks for 30 minutes per exercise session
- 7) Final treadmill test and blood sample

Why is this study being done?

African American (AA) men have the highest risk of prostate cancer in the world. In the United States the incidence of prostate cancer in A-A men is 65% greater than in Caucasian men. The exact cause for the increased incidence of prostate cancer in AA men is unknown. However, a diet high in fat and/or a sedentary lifestyle may predispose AA men to prostate cancer by affecting levels of different hormones in the blood that increases the growth of the cancer cells. Low levels of fitness have been associated with an increased risk of premature death from all causes and high levels of fitness are associated with many health benefits. The purpose of this study is to determine if walking on a treadmill 30 minutes a day for 12 days can improve the hormones in the blood that have been shown to increase the risk of developing prostate cancer in AA men and to see if 12 days of exercise will reduce the growth of prostate cancer cells.

How do you qualify for the study?

To qualify for the study you must be an African American male between the ages of 40 and 70 years, have a body mass index of >25 and ≤ 35 kg/m², weigh less than 375 pounds, have been sedentary for at least 6 months (not exercising for more than 20 minutes/2 days a week).

What will happen in the study?

This research is funded by the Department of Defense. The study will consist of two preliminary visits to the Howard University Cancer Center Biobehavioral Laboratory (room B118) followed by 12 visits to the laboratory to walk on the treadmill, then two final follow-up visits for a total of 16 visits to the laboratory.

At your first and final visits you will complete questionnaires (e.g. medical history, psychosocial, food frequency, and physical activity questionnaires). Your height, weight, hip, waist circumference, and body composition will be recorded. To measure your body composition you will stand on a scale that will determine the percent of your body that is composed of fat. A trained medical person will take a blood sample. Approximately one and a half ounces of blood will be drawn from your arm into four specimen test tubes for analysis of your levels of cholesterol, fats, testosterone, insulin, glucoses, PSA, sex hormone binding globulin (SHBG), and for genes that may relate to prostate cancer. In addition, some of your blood will be stored for later use in growing prostate cancer cells.

The treadmill test measures your level of physical fitness. The test will begin with walking at a slow speed (1.7 mph) up a grade of 10%. Every three minutes the speed and the grade will increase until you reach fatigue. During the treadmill test you will breathe through a mouthpiece and your exhaled air will be analyzed for concentrations of oxygen and carbon dioxide. Also during the treadmill exercise test your heart rate and blood pressure will be monitored. Heart rate is the number of times the heart beats per minute. Your heart rate will be determined using the electrocardiogram (ECG) attached to 10 electrodes placed on your chest. Your blood pressure will be measured using a blood pressure cuff. During the exercise test, you will be asked to rate how hard you are working (i.e. your level of fatigue). The treadmill exercise test will last for approximately 6-12 minutes.

The exercise program will consist of 30 minutes a day for 12 days (3 days a week for 4 weeks). The exercise will be walking on the treadmill. At the end of the 12 days you will have another blood sample taken, perform another exercise test, and have your weight and body fat measured.

What are the risks of the study?

The following risks are associated with your participation in this study. The risk of exercise testing in older men and women is 1 nonfatal event in 10,000 maximal treadmill tests and 1 fatal cardiac event in 70,000+ maximal exercise tests. Having the test administered by trained exercise physiology personnel will minimize these risks. All personnel will be trained in the use of an automated cardiac defibrillator and CPR. An emergency cart with the automated defibrillator will be present at all testing sessions. There is minimal risk of bruising and infection associated with blood drawing. These risks will be minimized by using aseptic techniques and by having experienced personnel draw all samples.

Are there benefits to take part in this study?

The benefits to you may consist of information regarding your level of fitness. The data collected may add to the body of knowledge regarding the risk for developing prostate cancer.

What are your rights if you take part in this study?

Taking part in this research study is your decision. You do not have to take part in this study, but if you do, you can stop at anytime. Your medical care now or in the future will not be affected by whether or not you take part in this study.

The investigators may stop you from taking part in this study at any time if it is in your best interest.

What about confidentiality?

All information obtained from this study will be tabulated by number and not by name. All of the individual results will be kept in Dr. Teletia Taylor's office in a locked file cabinet. Thus, confidentiality will be maintained and your name will never be used when the results of this study are discussed or published. Representatives of the U.S. Army Medical Research and Material Command are eligible to review research records as a part of their responsibility to protect human subjects in research.

What happens if you are injured because you took part in this study?

In the event of physical or other injury resulting from the research test(s) or procedure(s), emergency medical treatment will be provided. No funds have been set aside to compensate you if you are injured.

Who can answer your questions?

The Howard University Institutional Review Board will have access to the records of this project. Dr. Teletia Taylor can be reached at the following telephone number (202) 806-

4199 (E-mail address: t_r_taylor@howard.edu) and Dr. Deborah Williams can be reached at (202) 865-6791 in the event that you have any questions regarding participation in this project. **If you have any questions at any time and would like to discuss them with someone other than the investigators on this project, you are free to call the Office of the Executive Secretary, Howard University Institutional Review Board at the following telephone number (202) 806-7818.**

I have read the above description of the research project. Dr. Teletia Taylor and/or her staff have explained anything that I did not understand to me, and I have had all my questions answered to my satisfaction. I agree to participate in the project. I am informed that I must have a signed copy of the consent form before participating in the study.

I, _____ state that I am 18-years-of-age or older. I wish to participate in this research project being conducted by Dr. Teletia Taylor who is a researcher at the Howard University Cancer Center. I am informed that all tests and procedures are free and will be conducted in the Howard University Cancer Center Clinical Biobehavioral Laboratory (room B118).

I, _____ (check appropriate box) _____ give _____do not give permission to Dr. Teletia Taylor to store my blood to conduct future studies. These future studies will be strictly research tests that would look at my blood sample for possible genes and hormones that may be related to the causes of cancer and may help determine how my level of fitness may influence cancer prevention. Sign initials here:

I, _____ hereby acknowledge that I have received a copy of the Informed Consent Form.

Signature of Participant

Date

I, the undersigned, have defined and fully explained the tests or procedures involved in this investigation to the above participant.

Signature of Individual Obtaining Consent

Date

Investigator's Signature

Date